Amtd. dated October 7, 2005

Reply to Office Action of May 9, 2005

**Amendments to the Claims:** 

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:** 

1. (currently amended): A valve for use in a chest drainage device including an

upstream chamber and a downstream chamber, said upstream chamber and downstream chamber

defining a an air flow path, said valve disposed along the flow path and, said chest drainage

<u>device</u> comprising:

an inlet to the chest drainage device adapted to receive liquid and air from a

patient, a liquid collection chamber for collecting liquid,

a valve element separating the upstream chamber from the downstream chamber

secured to a wall defining the flowpath and having a first and a second sealing surface that are

opposed so that, when the first and second sealing surfaces are in contact, air will be prevented

from moving from the downstream chamber to the upstream chamber, and when the upstream

chamber is at a higher pressure than the downstream chamber, the sealing surfaces will separate

allowing air to move from the upstream chamber toward the downstream chamber, and,

a pressure relief actuating element located adjacent the valve element such that,

when the downstream chamber is at a higher pressure than the upstream chamber and a pressure

difference between the two chambers is above predetermined differential value, the valve

element deforms and contacts the pressure relief actuating element so that the pressure relief

actuating element causes the first and second sealing surfaces to separate.

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2. (original): The valve recited in claim 1, wherein the valve element includes two generally planar surfaces, and the first and second sealing surfaces extend along a line formed by the intersection of the two planar surfaces.

3. (original): The valve recited in claim 2, wherein the planar surfaces have reinforcement elements for support.

4. (original): The valve recited in claim 1, wherein the valve element includes two facets and the first and second sealing surfaces extend along a line formed by the intersection of the two facets and further comprising structural reinforcement elements that protrude from the planar surfaces.

- 5. (original): The dual protection valve recited in claim 4, wherein the reinforcement elements are generally perpendicular to the line formed by the intersection of the two sealing surfaces.
- 6. (currently amended): The valve recited in claim-4, A valve for use in a device including an upstream chamber and a downstream chamber, said upstream chamber and downstream chamber defining a flow path, said valve disposed along the flow path, said chest drainage device comprising:

a valve element separating the upstream chamber from the downstream chamber and having a first and a second sealing surface that are opposed so that, when the first and second sealing surfaces are in contact, air will be prevented from moving from the downstream chamber to the upstream chamber, and when the upstream chamber is at a higher pressure than

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the downstream chamber, the sealing surfaces will separate allowing air to move from the upstream chamber toward the downstream chamber, and,

a pressure relief actuating element located adjacent the valve element such that,
when the downstream chamber is at a higher pressure than the upstream chamber and a pressure
difference between the two chambers is above predetermined differential value, the valve
element deforms and contacts the pressure relief actuating element so that the pressure relief
actuating element causes the first and second sealing surfaces to separate,

wherein the valve element includes two facets and the first and second sealing surfaces extend along a line formed by the intersection of the two facets and further comprising structural reinforcement elements that protrude from the planar surfaces,

wherein each reinforcement element that protrudes from the planar surfaces has a width and the width varies among different reinforcement elements.

- 7. (original): The valve recited in claim 6 wherein the facets have a longitudinal distance and the reinforcement element at the location of the longest longitudinal distance has the greatest width.
- 8. (currently amended): The valve recited in claim-1 A valve for use in a device including an upstream chamber and a downstream chamber, said upstream chamber and downstream chamber defining a flow path, said valve disposed along the flow path, said chest drainage device comprising:

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a valve element separating the upstream chamber from the downstream chamber and having a first and a second sealing surface that are opposed so that, when the first and second sealing surfaces are in contact, air will be prevented from moving from the downstream chamber to the upstream chamber, and when the upstream chamber is at a higher pressure than the downstream chamber, the sealing surfaces will separate allowing air to move from the upstream chamber toward the downstream chamber, and.

a pressure relief actuating element located adjacent the valve element such that, when the downstream chamber is at a higher pressure than the upstream chamber and a pressure difference between the two chambers is above predetermined differential value, the valve element deforms and contacts the pressure relief actuating element so that the pressure relief actuating element causes the first and second sealing surfaces to separate, further comprising a diaphragm that is constructed to deform in a manner such that the valve element contacts the pressure relief actuating element when the predetermined pressure differential value is achieved, causing the first and second sealing surfaces to at least partially open to allow air into the upstream chamber.

9. (original): A valve separating an upstream side from a downstream side in a flow path, said valve comprising:

a valve element which includes a first and second opposed sealing surfaces, the valve element also including a diaphragm having a first surface, and a periphery that generally forms a flange,

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a base member having a generally circular longitudinal cross-section with a lumen

for the passage of air through the base, and,

a pressure relief actuating element disposed on the base and projecting in an axial

direction toward the sealing surfaces and adjacent the valve element, wherein the pressure relief

actuating element opens the sealing surfaces when the pressure in the upstream side is lower than

the pressure downstream side and the pressure difference between the sides exceeds a

predetermined limit.

10. (original): The valve recited in claim 8 wherein the valve further comprises:

a cap member having a generally circular longitudinal cross-section with a lumen

for the passage of air through the cap, the cap and the base being configured to secure the valve

element.

11. (original): The valve recited in claim 9, wherein the sealing surfaces generally

form a line.

12. (original): The valve recited in claim 9, wherein the valve element has two

generally planar surfaces that intersect at a line perpendicular to the axis of the valve element,

and the sealing surfaces are generally located at the intersection of the planar surfaces.

13. (original): The valve recited in claim 9, wherein the two generally planar surfaces

have reinforcing members.

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14. (original): The valve recited in claim 13, wherein the reinforcing members are

generally perpendicular to a line created by the sealing surfaces.

15. (original): The valve recited in claim 14 wherein each reinforcing member has a

width and the width of the reinforcing members varies.

16. (original): The valve recited in claim 12, wherein the pressure relief actuating

element is disposed adjacent the planar surfaces and, when the pressure on the downstream side

is higher than the pressure on the upstream side and the pressure difference between the sides

exceeds the predetermined limit, the valve element deforms and contacts the pressure relief

actuating element causing the first and second sealing members to open.

17. (original): The valve recited in claim 16, wherein the reinforcing members are

generally perpendicular to a line created by the sealing surfaces and wherein each reinforcing

member has a width and the width of the reinforcing members varies.

18. (currently amended): A chest drainage device for draining fluids from the chest,

the chest drainage device comprising an inlet, an outlet, a fluid liquid collection chamber for

collecting fluid liquid and a an air flow path for air between the inlet and outlet, the fluid air flow

path including an upstream side located toward the inlet and a downstream side located toward

the outlet,

a valve element disposed at a location along the air flow path adapted to prevent fluid air

flow from the downstream side toward the upstream side and having a first and a second sealing

surface that are opposed so that, when the first and second sealing surfaces are in contact, air will

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be prevented from moving from the downstream side to the upstream side, and when the upstream side is at a higher pressure than the downstream side, the sealing surfaces will separate allowing air to move from the upstream side to the downstream side, where the valve element is secured to a wall defining the flow path, and

a pressure relief actuating element disposed proximate to the sealing surfaces such that, when the downstream side is at a higher pressure than the upstream side and the pressure difference between the two sides exceeds a predetermined value, the valve element contacts the pressure relief actuating element such that the first and second sealing surfaces separate to decrease the pressure difference between the downstream side and the upstream side.

- 19. (original): The chest drainage device recited in claim 18, wherein the valve element has a generally tapered section and the pressure relief actuating element is located at an axially central location.
- 20. (currently amended): A chest drainage device for draining fluids from the chest, the chest drainage device comprising an inlet, an outlet, a fluid collection chamber for collecting fluid and a flow path for air between the inlet and outlet, the fluid flow path including an upstream side located toward the inlet and a downstream side located toward the outlet,

a valve element disposed at a location along the flow path adapted to prevent fluid air flow from the downstream side toward the upstream side and having a first and a second sealing surface that are opposed so that, when the first and second sealing surfaces are in contact, air will be prevented from moving from the downstream side to the upstream side, and when the

upstream side is at a higher pressure than the downstream side, the sealing surfaces will separate allowing air to move from the upstream side to the downstream side, and

that, when the downstream side is at a higher pressure than the upstream side and the pressure difference between the two sides exceeds a predetermined value, the valve element contacts the pressure relief actuating element such that the first and second sealing surfaces separate to decrease the pressure difference between the downstream side and the upstream side,

The chest drainage device recited in claim 18 wherein the valve element has a radially extending diaphragm portion and, when the downstream side is at a higher pressure than the upstream side and the pressure difference between the two sides equals a predetermined value, the pressure difference causes the diaphragm portion to deform such that sealing surfaces are separated by the pressure relief actuating element.

- 21. (original): The chest drainage device recited in claim 18, wherein the valve element includes two surfaces which taper towards the sealing surfaces, and the first and second sealing surfaces extend along a line formed by the intersection of the two surfaces.
- 22. (original): The chest drainage device recited in claim 18, wherein the valve element surfaces are generally flat.
- 23. (original): The chest drainage device recited in claim 18, wherein the valve element surfaces have reinforcing members to increase the stiffness of the valve element along a longitudinal direction.

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24. (original): The chest drainage device recited in claim 23, wherein the reinforcing

members are generally perpendicular to the line formed by the intersection of the two surfaces.

25. (original): The chest drainage device recited in claim 23 wherein the reinforcing

members do not substantially increase the force required to open the valve when the pressure is

higher in the upstream location than the downstream location.

26. (original): The chest drainage device recited in claim 18, wherein the valve

element is constructed to displace in a manner to contact the pressure relief actuating element

when the downstream side is at a higher pressure than the upstream side, and the pressure

difference between the two sides equaling a predetermined pressure differential value, such that

first and second sealing surfaces at least partially open to allow air into the upstream chamber.

27. (currently amended): A valve that is adapted to be disposed along a flow path

from a region upstream of the valve to a region downstream of the valve, the valve comprising

a valve element which is adapted to allow flow from an upstream location to a

downstream location during conditions of positive relative pressure, said positive relative

pressure condition being when the upstream pressure is relatively higher than downstream

pressure, the valve element further adapted to prevent flow from the region downstream to a

region upstream under a predetermined range of conditions of negative relative pressures, said

negative relative pressure conditions being when the upstream pressure is relatively lower than

downstream pressure, and,

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a pressure relief actuating element disposed on the valve proximate the valve element such that the valve element does not contact the pressure relief actuating element when the negative relative pressure does not exceed a predetermined limit, and wherein the valve element and the pressure relief actuating element contact when the negative relative pressure exceeds the predetermined limit such that the valve element allows flow to pass from the

downstream side to the upstream side,

wherein the valve element includes a diaphragm that deforms and causes the valve element to contact the pressure relief actuating element and allow flow from the downstream side to the upstream side when the negative relative pressure exceeds the

predetermined limit.

28. (cancelled)

29. (original): The valve of claim 27 wherein the pressure relief actuating element is

disposed along an axial direction and the diaphragm is disposed along a position transverse the

axial direction.

30. (original): The valve of claim 27, wherein the predetermined limit is between -30

and -100 cm of water.

31. (original): The valve of claim 27 wherein the valve allows a flow rate of at least

15 liters per minute at a positive pressure differential of 40 cm of water.

32. (currently amended): The valve of claim 28 27 wherein the valve element

includes tapered sides and a valve seal is formed at the intersection of the tapered sides.

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- 33. (original): The valve of claim 26 further comprising a cap and a base, and wherein the valve element is disposed between the cap and the base.
- 34. (original): The valve of claim 33 wherein the valve element sides have reinforcing members disposed along a longitudinal direction.
- 35. (original): The valve of claim 34 wherein the reinforcing members have a width and the width of the reinforcing members varies.